November 22, 2021

Bacchus Vascular, Inc.
Gregory Mathison
VP, Clinical & Regulatory Affairs, QA
3110 Coronado Dr.
Santa Clara, California 95054

Re: K023514
Trade/Device Name: Trellis Reserve Infusion System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEY, KRA

Dear Gregory Mathison:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated December 2, 2002. Specifically, FDA is updating this SE Letter as an administrative correction because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2021.11.22 13:29:43 -05'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 2 2002

Bacchus Vascular, Inc.
c/o Mr. Gregory J. Mathison
Vice President, Clinical Affairs, Regulatory Affairs,
Quality Assurance
3110 Coronado Drive
Santa Clara, CA 95054

Re: K023514
Trade Name: Trellis Reserve Infusion System
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II (two)
Product Code: KRA
Dated: November 21, 2002
Received: November 22, 2002

Dear Mr. Mathison:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):	This application
Device Name:	Trellis Reserve Infusion System
Indications for Use:	The Trellis™ Reserve Infusion System is intended for controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K023514

1C023514

DEC 0 2 2002

ATTACHMENT E

510(k) SUMMARY

510(k) Summary

General Information

Classification	Class II
Trade Name	Trellis™ Reserve Infusion System
Submitter	Bacchus Vascular, Inc. 3110 Coronado Drive Santa Clara, CA 95054 408-980-8300
Contact	Gregory J. Mathison Vice President, Regulatory, Clinical Affairs & Quality Assurance

Intended Use

The Trellis™ Reserve Infusion System is intended for controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

Predicate Devices

Trellis Infusion System	K013635	Manufactured by Bacchus Vascular, Inc.
Trellis Plus Infusion System	K021958	Manufactured by Bacchus Vascular, Inc.

Device Description

The Trellis Reserve Infusion Catheter enables the physician to isolate a treatment region, infuse a physician-specified fluid, and disperse the fluid by means of oscillation of a Dispersion Wire. The Isolation/Infusion component is a multi-lumen catheter with two compliant balloons at the distal end and infusion holes located between these balloons. When inflated, the compliant balloons isolate a treatment zone to maintain concentration of the infused fluid. The device also has a central through-lumen that is compatible with a 0.035" guidewire. The Dispersion Wire component is a sheathed, shape-set Nitinol cable that provides oscillation when activated. The Dispersion Wire is connected to an integral Oscillation Drive Unit which oscillates the Dispersion Wire up to 25 Hertz within the isolated region to further disperse the infused fluid. If desired by the physician, post procedure aspiration of the isolated area between the occluding balloons may be accomplished through the catheter by using the guidewire lumen.

Materials

All materials used in the manufacture of the Trellis Reserve are suitable for this use and have been used in numerous previously cleared products.

Testing Summary

The Trellis Reserve Infusion System was tested in the same manner as the Trellis and Trellis Plus Infusion Systems (K013635 & K021958). All components, subassemblies, and/or full devices met the required specifications for the completed tests. The Trellis Reserve was designed under the Bacchus Quality System which is in compliance with 21CFR§820.30.

Summary of Substantial Equivalence

The Trellis Reserve Infusion System is equivalent to the predicate product, the Trellis Plus Infusion System. The indications for use, function, methods of manufacturing, and materials used are substantially equivalent. Bacchus Vascular, Inc. believes the Trellis Reserve Infusion System is substantially equivalent to existing legally marketed devices.

Indications for Use

510(k) Number (if known):	This application
Device Name:	Trellis Reserve Infusion System
Indications for Use:	The Trellis™ Reserve Infusion System is intended for controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K023514